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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/446,681 | 03/14/2000 | JOHN ANTHONY CHARLES ARCHER | | 2724 |

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|---|---|
| SANDALS, WILLIAM O | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | 14 |

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/446,681 | Applicant(s) Archer et al. |
|---|---|---|
| | Examiner William Sandals | Art Unit 1636 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Jan 10, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *30-35, 37, and 49-60* is/are pending in the application.

4a) Of the above, claim(s) *31 and 49* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *30, 32-35, 37, and 50-60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Mar 14, 2000* is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

## DETAILED ACTION

### *Election/Restriction*

1. Claims 31 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of Groups XII and XIV respectively, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12, filed January 10, 2002.

2. Applicant's election without traverse of Group VI, claims 30, 32-35, 37 and 50-60 in Paper No. 12 is acknowledged.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Drawings*

4. New formal drawings are required in this application because recent changes to the MPEP, section 608.02(c) no longer allow deferral of submission of drawings pursuant to notification. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

***Specification***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

6. Sequences are claimed in claims 51-55 without the proper SEQ ID NO: identifiers. Sequences appear without sequence identifiers in Figure 4 and at pages 35 and 36 for example. All occurrences must be corrected.

7. Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claim 52 is drawn to a nucleic acid molecule from codon 295 to codon 1035 of the sequence shown in figure 4. Claim 52 depends from claim 51 which claims a nucleic acid molecule from codon 295 to codon 1035 of the sequence shown in figure 4. Claim 52 is therefore drawn to the identical subject matter of claim 51.

### *Claim Rejections - 35 USC § 112*

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification lacks complete deposit information for the deposit of the vector pJP7 containing the nucleic acid sequence as claimed. Because it does not appear that the vector pJP7 containing the nucleic acid sequence as claimed is known and publicly available or can be reproducibly isolated from nature without undue experimentation, a suitable deposit for patent purposes is required.

No information regarding a deposit of the vector pJP7 containing the nucleic acid sequence as claimed in the specification is found. Therefore there is insufficient assurance that all required deposits have been made and all the conditions of M.P.E.P. 608.01(p)(C) are met because:

a- If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that **the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.** See 37 CFR 1.808.

-or-

b- If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

9. Amendment of the specification to conform to either a- or b- above is required.

10. Claim 34 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth above.

11. Claims 30, 32-35, 37 and 50-60 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Teachings on the actual activity of the regulatory protein of claim 50 is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The claims are drawn to an isolated nucleic acid comprising the sequence encoding a regulatory protein in the ohp operon, a vector containing the regulatory protein, a host cell transformed with the vector and a method of using the vector. In order to make and use the claimed nucleic acid undue experimentation is required. Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors. Many of these factors have been summarized in *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

The Wands factors as they apply to the instant claimed invention are as follows:

a- The quantity of experimentation necessary to reduce the instant claimed invention to practice would involve demonstration that the regulatory protein is in fact a regulatory protein.

b- Guidance is provided as to how one of skill in the art may go about finding out if the claimed putative regulatory protein is in fact a regulatory protein.

c- No examples are provided of the regulatory protein.

d- The nature of the invention is complex. The ohp operon of *Rhodococcus* is previously unknown. The structural, functional and biochemical features of the ohp operon of *Rhodococcus* have not been described by the instant specification, nor by those of skill in the art.

e- The state of the art has not shown an ohp operon in *Rhodococcus*.

f- Those of skill in the art have shown that the only way to demonstrate that a putative protein regulates expression from a promoter is to actually produce the regulatory protein and test for it's regulatory activity with the desired target promoter sequence. Other operons in *Rhodococcus* which have recently been demonstrated by EP 719 862 (see especially page 2, lines 18-37) and EP 713 914 (see especially page 2, lines 22-26, and 31-35, page 3, lines 28-30) have shown the level of experimentation and guidance necessary to demonstrate the possession of a regulatory protein. Each of EP 719 862 and EP 713 914 states that one of skill in the art would not know which proteins, if any would act as regulatory proteins until and unless the protein is expressed and then tested to see if it is indeed a regulatory protein which acts on the desired target promoter sequence to control expression from that promoter sequence.

g- Li et al. (of record; see especially the discussion at page 6416, column 2, first full paragraph) taught the inability to predict the existence of a regulatory protein from inferential data, and from comparisons to similar operons from other bacteria. In short, the only way to accurately and definitely show the existence of a regulatory protein is to express it in conjunction with the target promoter sequence and show that the regulatory protein does regulate expression from the desired promoter.

h- Since the only evidence that has been presented in the specification to support the claim to a regulatory protein is an inference from sequence information, where the specification states that the nucleic acid sequence of the putative regulatory protein is physically located in a nucleic acid sequence near a putative ohp operon protein. The putative ohp operon protein is also inferred from sequence data. A region of nucleic acid between the putative regulatory protein and the putative ohp operon protein is also speculated to contain a putative promoter region. It is merely assumed that the putative regulatory protein acts on the putative promoter region.

i- Therefore, given the analysis above, it must be considered that the skilled artisan would have needed to have practiced considerable non-routine, trial and error experimentation to practice the claimed invention.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 30, 32-35, 37 and 50-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 50 recites the limitation "modification thereof" in line 4. One of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation, since a

modification of a nucleic acid sequence may consist of a single nucleotide or even a sugar molecule.

15. Claim 57 recites the limitation "a vector" in line 1. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 58 provides for the use of a vector, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 58 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Conclusion***

17. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or

applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

March 8, 2002